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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,493	07/19/2000	Norman Nashed	SCH-1686-C1	1582

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/01/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/619,493

Applicant(s)

Norman Mashed

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 2, 9-11, 14, and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-8, 12, 13, 15-17, and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 2, 9-11, 14, and 18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Final office Action on Merits

Invention: Instant invention is drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering gestagen, estrogen and/or the combination thereof.

Status of the application

Claims 1-23 are pending.

Claims 3-8, 12, 13, 15-17 and 19-23 are rejected and 1,2,9-11, 14 and 18 are withdrawn from consideration as non elected invention.

No claim is allowed.

Response filed in paper no. 8 and IDS in paper no. 9 is hereby acknowledged.

Traversal on restriction requirement was addressed in our previous action. Inventions are distinct. Claims are drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering gestagen, which is broad and includes dozens of compounds which does not fall in the same class or subclass. Furthermore, methods for treating premenstrual dysphoric disorder (PMDD) by administering estrogen compounds and their mixtures are also claimed which would require different searches. It would be a burden on the examiner to search the whole invention as claimed. The search was limited to the combination of the elected species. This was considered a reasonable search according to MPEP 803.02. Burden is likewise demonstrated by divergent classification, database and other searches for the entire genus would represent

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excessive burden on the examiner. For the reason cited above and in previous office action the examination of the elected invention is proper.

Claims 3-8, 12, 13, 15-17 and 19-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Claims 3-8, 12, 13, 15-17 and 19-23 and Neuman, Friedmund (CA 118:161077, abstract of Pharm. Ztg. (1992), 137(34), 9-15) for the same reasons set forth in our previous office action. Neuman teaches the application of estrogen-progestogen drug combination in gynecology, both for contraception and for the treatment of various disorders such as premenstrual syndrome etc. The application forms and side effects are also described.

Guenther et al. (CA 113:218253, abstract of WO 9004397). Guenther teaches the preparations of estrogen-gestodene drug combination for the treatment of premenstrual syndrome etc.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Non elected invention must be canceled.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

6/26/02


SABIHA QAZI, PH.D
PRIMARY EXAMINER